

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN**

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**BAYER HEALTHCARE, LLC,**

**Plaintiff-Counterclaim Defendant,**

**v.**

**Case No. 08-C-0953  
(Consolidated With  
Case No. 09-C-0108)**

**NORBROOK LABORATORIES, LTD.,  
and NORBROOK, INC. USA,**

**Defendants-Counterclaimants.**

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**DECISION AND ORDER**

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This matter is before the Court on the motion of Defendants Norbrook Laboratories, Ltd. and Norbrook, Inc. U.S.A. (collectively referred to as “Norbrook”) for reconsideration pursuant to Rule 54(b) of the Federal Rules of Civil Procedure, or in the alternative, for certification of an interlocutory appeal pursuant to 28 U.S.C. § 1292(b) and a stay of the proceedings during that appeal. Norbrook’s motion addresses this Court’s September 23, 2009, Decision and Order denying Norbrook’s motion for judgment on the pleadings, pursuant to Rule 12(c) of the Federal Rules of Civil Procedure, seeking dismissal of the Complaint for failure to state a claim and for lack of subject matter jurisdiction. Also pending is Bayer’s motion to compel discovery.

The action relates to United States Patent Number 5,756,506 (the “506 patent”) and arises out of Norbrook’s filing of an Abbreviated New Animal Drug Application

(“ANADA”) with the United States Food and Drug Administration (“FDA”) seeking approval to manufacture and sell in the United States a generic version of the injectable animal drug product BAYTRIL® 100, prior to the expiration of the ‘506 patent.

### **Reconsideration**

In addressing Norbrook’s motion for reconsideration, the Court will not reiterate the rather complex relevant statutory and factual background of the case. (*See* September 23, 2009, Decision and Order, 5-12). Instead familiarity is assumed.

With respect to Bayer’s claim under § 271(e)(2)(B) of Title 35 of the United States Code, the Court concluded that Norbrook had not established that, as a matter of law, Bayer failed to state a cause of action under § 271(e)(2)(B). The Court noted that the parties disputed the validity of Norbrook’s purported withdrawal of its Paragraph IV certification and whether it was appropriate for Norbrook to file a Section I statement. Viewing the facts and construing all inferences from those facts in favor of Bayer, this Court could not find that Norbrook had established that the FDA will approve the amendment and, therefore, conclude that the alleged infringing use is different. In addition, the Court determined that, even accepting that the December 1, 2008, amendment was effective, Norbrook had not established that to state a cause of action under § 271(e)(2) an ANADA must “contain” a Paragraph IV certification.

The Court also rejected Norbrook’s contention that, as a matter of law, Bayer could not establish an infringing “use” under § 271(e)(2). In making that determination, the Court analyzed *Purepac Pharmaceutical Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir.

2004), relied upon by Norbrook, and rejected Norbrook's contention that factual similarities between *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), and the instant action demonstrated that Bayer's § 271(e)(2) claim could not succeed. The Court also rejected Norbrook's contention that Bayer's § 271(b) and § 271(c) claims could not succeed, relying on its determination that Norbrook had not established that Bayer failed to state a § 271(e)(2) claim. The Court also determined that *Takeda Pharmaceuticals Co. v. Sandoz, Inc.*, No. 07 Civ. 3844, 2007 WL 2936208, \*3-4 (S.D.N.Y. Oct. 9, 2007), supported its conclusion that Bayer's claims of contributory and induced infringement should not be dismissed on the pleadings.

Additionally, the Court concluded that Bayer had satisfied its burden of establishing that the Court has subject matter jurisdiction over the action pursuant to 28 U.S.C. § 1338(a), relying on its determination that Bayer had stated a § 271(e)(2) infringement claim. Although Norbrook contended that it only sought approval for the multiple-day low-dose treatment, the Court concluded that Norbrook had not established that it could accomplish that goal without a Paragraph IV certification.

With respect to Bayer's declaratory judgment claim, the Court concluded that Norbrook's purported withdrawal of its Paragraph IV certification was not dispositive of Bayer's declaratory judgment claim and that the circumstances of the action are sufficiently analogous to those of *Teva Pharmaceuticals* and established the existence of an Article III "controversy." (Court's September 23, 2009, Decision and Order at 27-28 (citing *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007))).

Norbrook seeks reconsideration, pursuant to the second sentence of Rule 54(b), which states that “any order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties’ rights and liabilities.”

A district court will grant a motion for reconsideration when: (1) the court has patently misunderstood a party; (2) the court has made a decision outside the adversarial issues presented to the court by the parties; (3) the court has made an error not of reasoning but of apprehension; (4) there has been a controlling or significant change in the law since the submission of the issue to the court; or (5) there has been a controlling or significant change in the facts since the submission of the issue to the court. *Bank of Waunakee v. Rochester Cheese Sales Inc.*, 906 F.2d 1185, 1191 (7th Cir. 1990). Motions for reconsideration serve a limited function: to correct manifest errors of law or fact or to present newly discovered evidence. *Caisse Nationale de Credit Agricole v. CBI Indus., Inc.*, 90 F.3d 1264, 1269 (7th Cir. 1996). “Reconsideration is not an appropriate forum for rehashing previously rejected arguments or arguing matters that could have been heard during the pendency of the previous motion.” *Id.*

By its motion for reconsideration, Norbrook argues that the Court’s decision is incorrect. Norbrook highlights the scope of the ‘506 patent, the purported “amendment” of its ANADA with a Section I statement, and that the Court could take judicial notice of matters in the public record without converting Norbrook’s motion for judgment on the

pleadings. Norbrook also argues that the Court's decision overlooks or misapprehended FDA regulations governing amendments to ANADAs and offered a statutory interpretation of the phrase "the use of which is claimed in a patent" in 35 U.S.C. § 271(e)(2) that conflicts with the statute's language and the purpose of creating an artificial act of infringement. In addition, Norbrook contends that the decision overlooked the application of the plausibility standard of *Ashcroft v. Iqbal*, 556 U.S. \_\_\_\_, 129 S.Ct. 1937, 1940-50 (2009) to the inducement to infringe and contributory infringement claims, and misapprehended whether there is a case or controversy between the parties.

Bayer asserts that Norbrook's attempt to obtain summary judgment through its motion for judgment on the pleadings should again be denied, and that the Court's analysis of § 271(e)(2), Bayer's §§ 271(b) and (c) claims, and its declaratory judgment claims was correct.

A threshold issue raised by Norbrook's motion for reconsideration is the Court's decision to exclude from its consideration matters outside the pleadings. Both Bayer and Norbrook submitted materials outside the pleadings in conjunction with the motion for judgment on the pleadings.<sup>1</sup> However, neither party addressed the impact of those materials

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<sup>1</sup>In opposition to Norbrook's motion for judgment on the pleadings, Bayer filed the Declaration of Jamie Simpson ("Simpson Decl.") proffering the following evidentiary material outside the pleadings: Ex. C (Defs.' Resp. Pl.'s First Set Interrogs.); Ex. D (Portions of the Defs.' Rule 30(b)(6) William G. Zollers, Jr. April 10, 2009, Dep. ("Rule 30(b)(6) Zollers Dep."); Ex. E-G (E-mails from the FDA to Defs. dated Feb. 24, 2009, Nov. 25, 2008, & Dec. 15, 2006, respectively); Ex. H (Defs.' Internal E-mail dated July 2, 2008); and, Ex. I (E-mail from Norbrook to the FDA dated Sept. 18, 2008.)

With Norbrook's reply memorandum in support of its motion for judgment on the pleadings, Norbrook filed the following evidentiary material outside the pleadings with the Declaration of Eric Lobenfeld ("Lobenfeld Decl."): Ex. A (FDA Citizen Pet. Resp., Docket No. FDA-2003-P-0321/CPI dated April 6, 2004); Ex. B (Bayer Citizen Pet. submitted to the FDA dated June 13, 2006); Ex. C (Portions of Rule 30(b)(6) Zollers Dep.); Ex. I (Defs.' Supplemental Resps. Pl.'s First Set Interrogs. Nos. 3 & 5 served on April 9, 2009); and, Ex. J (Defs.' Resps. Pl.'s First Set Interrogs. served March 17, 2009).

on the motion in conjunction with Rule 12(d) of the Federal Rules of Civil Procedure. In the exercise of its discretion, the Court decided to exclude the extraneous material “[b]ecause the motion for judgment on the pleadings was filed early in the proceedings and the parties have only engaged in limited discovery, and the issues involved in this litigation are complex.” (Court’s September 23, 2009, Decision and Order 3.)

Norbrook’s argument that a court may take judicial notice of matters in the public record is made belatedly. The role of the Court is not to make arguments for the parties. In the exercise of its discretion, the Court decided to exclude all materials outside the pleadings from consideration on Norbrook’s motion for judgment on the pleadings. Norbrook does not contend that the Court made a manifest error of law in exercising its discretion as to how to manage the parties’ submissions of materials outside the pleadings in conjunction with the motion for judgment on the pleadings. Norbrook has not established a basis for a reconsideration on that ground.

The substantive legal issues raised by Norbrook revisit the Court’s analysis. In part, Norbrook rehashes its prior arguments and, in part, Norbrook seeks a new decision based upon the materials that the Court excluded from consideration. The Court’s rulings rest on its deliberation of the pleadings, the relevant statute and regulations, and the applicable case law. While Norbrook’s contentions are not devoid of support, its motion is, in essence, a request that the Court reverse each of its prior determinations by accepting the arguments previously advanced by Norbrook. Since Norbrook has not established that the Court committed a manifest error of law, its motion for reconsideration is denied.

## Interlocutory Appeal

Next, the Court considers Norbrook's alternative request, for certification for interlocutory appeal. Bayer asserts that the request for the interlocutory appeal should be denied because the Federal Circuit has passed on the issue that Norbrook seeks to contest and, that, regardless of the appeals court's ruling on the issue, the appeal would not speed up the litigation or dispose of the case since it would only control Bayer's § 271(e)(2) claim.

Interlocutory appeal is afforded by Section 1292(b) of Title 28 of the United States Code, which provides:

When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order.

Section 1292(b) "must be used sparingly lest interlocutory review increase the time and expense required for litigation." *Asher v. Baxter Int'l. Inc.*, 505 F.3d 736, 741 (7th Cir. 2007).

### *Question of Law*

The first statutory criterion under § 1292(b) is that there must be a question of law. The question of the proper interpretation of § 271(e) and whether Bayer may maintain its patent infringement action against Norbrook based on the pleadings in this action is a pure question of law. Thus, Norbrook's request meets the first statutory criterion.

### *Controlling*

The second statutory criterion under § 1292(b) is that the question of law must be controlling. The cases do not interpret the term literally. *Sokaogon Gaming Enter. Corp. v. Tushie-Montgomery Assocs., Inc.*, 86 F.3d 656, 659 (7th Cir. 1996). “A question of law may be deemed ‘controlling’ if its resolution is quite likely to affect the further course of the litigation, even if not certain to do so.” *Id.* (citing *Johnson v. Burken*, 930 F.2d 1202, 1205-06 (7th Cir. 1991); 16 Charles Alan Wright et al., *Federal Practice and Procedure* § 3930 at 159-60 & n.12 (1977)). If Norbrook prevailed on appeal, that ruling would be quite likely to affect the future course of this litigation. Thus, the issue would be controlling.

### *Contestable*

The third statutory criterion under § 1292(b) is that the question of law must be contestable; i.e., that “substantial grounds for a difference of opinion on the issue exist.” The issues presented by Norbrook’s motion for judgment on the pleadings have not previously been addressed by the Federal Circuit. As Norbrook states: “Given that both sides and the Court were analogizing to Hatch-Waxman cases involving, at best, somewhat analogous circumstances, at the very least, there is substantial ground for difference of opinion on this issue.” (Norbrook’s Mem. Supp. Mot. Recons. or Certification Interlocutory Appeal 18.) While the Court believes that its analysis of the issues is correct, Norbrook’s arguments are plausible and, given the fact that similar circumstances have not been addressed by the Federal Circuit, “substantial grounds for a difference of opinion on the issue



exist.” *See* 28 U.S.C. § 1292(b). Therefore, Norbrook’s request for an interlocutory appeal satisfies the third statutory criterion.

#### *Materially Advance Litigation*

The fourth statutory criterion under § 1292 is whether the appeal would materially advance the litigation; that is, “its resolution must promise to speed up the litigation.” 28 U.S.C. § 1292(b). If Norbrook prevails on appeal, the issues in this case will be substantially narrowed. Thus, an interlocutory appeal would materially advance this litigation.

The proposed appeal fulfills all the requisite criteria for an interlocutory appeal under § 1292. Therefore, this Court grants Norbrook’s petition for an interlocutory appeal, and will stay this matter until the Court of Appeals for the Federal Circuit resolves such appeal, including exercising its own discretion in deciding whether it will grant permission to appeal the interlocutory order certified by this Court. *See In re Convertible Rowing Exerciser Patent Litig.*, 903 F.2d 822 (Fed. Cir. 1990); 28 U.S.C. § 1292(b).

#### **Motion to Compel**

Also pending is Bayer’s motion to compel discovery that was filed before the Court issued its decision on Norbrook’s motion for judgment on the pleadings. The subject discovery disputes relate to the issues raised by the judgment on the pleadings. If the the appeals court accepts the matter for interlocutory appeal, its decision on those issues are likely to affect the disposition of the discovery issues and, perhaps, the entire action. Therefore, in

the interest of judicial economy and to save unnecessary expense for the parties, the Court will hold in abeyance Bayer's motion to compel until resolution of the interlocutory appeal.

**NOW, THEREFORE, BASED ON THE FOREGOING, IT IS HEREBY ORDERED THAT:**

Norbrook's motion for reconsideration pursuant to Rule 54(b) or in the alternative for certification of an interlocutory appeal (Docket No.101) is **DENIED** as to reconsideration and **GRANTED** as to the certification of this matter for interlocutory appeal and as to a stay of this matter until the resolution of those proceedings.

Bayer's motion to compel (Docket No. 79) is held in **ABEYANCE** pending resolution of the interlocutory appeal.

Dated at Milwaukee, Wisconsin this 20th day of January, 2010.

**BY THE COURT**

*s/ Rudolph T. Randa*

**Hon. Rudolph T. Randa**  
**U.S. District Judge**